

REMARKS

Claims 11 and 20-25 have been allowed. New claim 37 has been added. Support for new claim 37 may be found in the specification in experimental Example 2 at pages 36-38. Thus, Claims 11, 19-29 and 37 remain pending in the present application. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Rejection under 35 U.S.C. §102(e)

Claims 19 and 26-29 were rejected under 35 U.S.C. §102(e) as being anticipated by Toppo (US 6,048,903). The Examiner alleges that the prevention of cerebral apoplexy as recited in the present claims is inherent in the Methods of Toppo which are directed to the use of resveratrol for treatment of elevated LDL and for increasing levels of HDL in order to prevent the clogging of arteries.

In order to rely upon the theory of inherency, the Examiner must show that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. According to M.P.E.P. §2112 (IV):

“in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.

Toppo discloses nothing concerning cerebral apoplexy, much less identifying a patient at increased risk for cerebral apoplexy as recited in new claim 37. The disclosure of Toppo is limited to treatment of hypercholesterolemia by decreasing LDL and increasing HDL. Hypercholesterolemia has many effects, only one of which might be cerebral apoplexy. Moreover, cerebral apoplexy has many causes, only one of which might be hypercholesterolemia. Thus, treating hypercholesterolemia, as disclosed by Toppo patent, would certainly not necessarily result in prevention of cerebral apoplexy as presently claimed.

In support of this position, applicants hereby submit two references regarding the drug “Pravastatin sodium”, widely known as the trade name MELATONIN™ (Shepherd et al., *Lancet* 360: 1623-1630, 2002; Exhibit A and Shepherd et al., *New Engl. J. Med.* 333: 1301-1307, 1995; Exhibit B).

Exhibit A at page 1626, second paragraph, teaches that pravastatin lowered LDL levels by 34% and increased HDL levels by 5%. However, Table 2 of this reference (page 1625) teaches p values of 0.81 and 0.85 for "fatal or non-fatal stroke" and "non-fatal stroke", respectively, indicating that pravastatin has no significant therapeutic effect on stroke (cerebral apoplexy).

Similarly, Exhibit B teaches that pravastatin lowered HDL by 26% and increased HDL by 5% (page 1304, first paragraph). Table 2 of this reference (page 1303) discloses a p value of 0.57 for "fatal or nonfatal stroke", again showing that pravastatin has no significant therapeutic effect on stroke.

Thus, as evidenced by Exhibits A and B, although pravastatin treated hypercholesterolemia, it had no significant effect on the prevention of cerebral apoplexy (stroke). As such, prevention of cerebral apoplexy is not a necessary feature of a substance (such as pravastatin) that is capable of both decreasing levels of LDL and increasing levels of HDL. Since prevention of cerebral apoplexy is not a necessary feature of the disclosure of Toppo, Toppo does not provide an inherent teaching of such prevention. Thus, claims 19, 26-29 and 37 are not anticipated by Toppo, and Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 102(e).

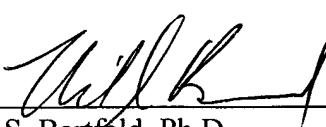
CONCLUSION

The present application is now believed to be in condition for immediate allowance, and such action is earnestly solicited. If any minor issues remain that could be resolved by telephone, the Examiner is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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